

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-26. (Cancelled)

27. (New) A unit dose of a therapeutic composition comprising about 16 to about 40  $\mu\text{g}$  budesonide, wherein the budesonide

(a) is in the form of finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20  $\mu\text{m}$ , and

(b) is suspended in an aqueous medium.

28. (New) A therapeutic method of treating a condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320  $\mu\text{g}$  per day, delivered as 8 or more unit doses in a metered amount of about 32  $\mu\text{g}$  budesonide per unit dose, wherein each unit dose comprises finely divided budesonide particles, at least 90% of which have a mass equivalent sphere diameter of less than 20  $\mu\text{m}$ , the particles being suspended in an aqueous medium.

29. (New) The therapeutic method of claim 28, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10  $\mu\text{m}$ .

30. (New) The therapeutic method of claim 28, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7  $\mu\text{m}$ .

31. (New) The therapeutic method of claim 28, wherein the amount of budesonide is about 256 µg per day.

32. (New) The therapeutic method of claim 28, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

33. (New) A unit dose of a therapeutic composition consisting of (a) about 32 µg budesonide; and (b) other ingredients comprising  
a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;  
dextrose;  
Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;  
disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and  
potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,  
wherein the budesonide is in the form of finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 µm, suspended in an aqueous medium, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

34. (New) The unit dose of claim 33, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 µm.

35. (New) The unit dose of claim 33, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 µm.

36. (New) A therapeutic method of treating a condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320 µg per day, delivered as 8 or more unit

doses, wherein each unit dose consists of about 32 µg budesonide and other ingredients, the other ingredients comprising

a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;

disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and

potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,

wherein the budesonide is in the form of finely divided particles, at least 90% having a mass equivalent sphere diameter of less than 20 µm, suspended in an aqueous medium.

37. (New) The therapeutic method of claim 36, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 µm.

38. (New) The therapeutic method of claim 36, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7 µm.

39. (New) The therapeutic method of claim 36, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

40. (New) A therapeutic method of treating or preventing a condition of the upper respiratory tract, the method comprising administering into a nostril of a mammal in need thereof a metered unit dose, the active ingredient of which consists of about 32 µg of budesonide formulated as finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20 µm, suspended in an aqueous medium.

41. (New) The therapeutic method of claim 40, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 µm.

42. (New) The therapeutic method of claim 40, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7  $\mu\text{m}$ .

43. (New) The therapeutic method of claim 40, wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide.

44. (New) A therapeutic method of treating a condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320  $\mu\text{g}$  per day, delivered as 8 or more unit doses, the active ingredient of each unit dose consisting of about 32  $\mu\text{g}$  budesonide formulated as finely divided particles, at least 90% of which have a mass equivalent sphere diameter of less than 20  $\mu\text{m}$ , suspended in an aqueous medium.

45. (New) The therapeutic method of claim 44, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10  $\mu\text{m}$ .

46. (New) The therapeutic method of claim 44, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7  $\mu\text{m}$ .

47. (New) The therapeutic method of claim 44, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

48. (New) A unit dose of a therapeutic composition, the active ingredient of which consists of about 32  $\mu\text{g}$  budesonide, wherein the therapeutic composition additionally comprises a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;  
dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;  
disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and  
potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,  
wherein the budesonide is in the form of finely divided particles, at least 90% of which  
have a mass equivalent sphere diameter of less than 20  $\mu\text{m}$ , suspended in an aqueous medium,  
said therapeutic composition being suitable for nasal administration to a mammal in a single  
dose.

49. (New) The unit dose of claim 48, wherein at least 80% of the particles have a  
mass equivalent sphere diameter of less than 10  $\mu\text{m}$ .

50. (New) The unit dose of claim 48, wherein at least 80% of the particles have a  
mass equivalent sphere diameter of less than 7  $\mu\text{m}$ .

51. (New) The unit dose of claim 48, wherein each unit dose contains about 0.6 to  
0.7 mg/ml budesonide.

52. (New) A unit dose of a therapeutic composition comprising about 32  $\mu\text{g}$   
budesonide, wherein the budesonide is in the form of finely divided particles and is suspended in  
an aqueous medium having a pH between 3.5 and 5.0, said composition being suitable for  
administration to a mammal in a single dose, wherein the composition includes no more than  
about 32  $\mu\text{g}$  budesonide.

53. (New) The unit dose of claim 52, wherein the pH of the aqueous medium is  
between 4.2 and 4.6.

54. (New) The unit dose of claim 52, wherein said composition is suitable for nasal  
administration to a mammal.

55. (New) The unit dose of claim 52, wherein the composition contains about 0.6 to 0.7 mg/ml budesonide.

56. (New) The unit dose of claim 52, further comprising one or more pharmaceutically acceptable additives selected from the group consisting of thickening agents, isotonicity agents, surfactants, chelating agents, and preservatives.

57. (New) A therapeutic method of treating or preventing a condition of the upper respiratory tract, the method comprising administering into a nostril of a mammal in need thereof a metered unit dose of finely divided budesonide particles suspended in an aqueous medium having a pH between 3.5 and 5.0, wherein said metered unit dose consists of about 32 µg budesonide and one or more ingredients other than budesonide.

58. (New) The therapeutic method of claim 57, wherein the pH of the aqueous medium is between 4.2 and 4.6.

59. (New) The therapeutic method of claim 57, wherein the condition to be treated is seasonal allergic rhinitis.

60. (New) The therapeutic method of claim 57, wherein the condition to be treated is perennial allergic rhinitis.

61. (New) The therapeutic method of claim 57, wherein the condition to be treated is perennial non-allergic rhinitis.

62. (New) The therapeutic method of claim 57, wherein the condition to be treated is chronic sinusitis.

63. (New) The therapeutic method of claim 57, wherein the condition to be treated is recurrent sinusitis.

64. (New) The therapeutic method of claim 57, wherein the condition to be treated is nasal polyps.

65. (New) The therapeutic method of claim 57, wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide.

66. (New) A therapeutic method of treating a condition of the upper respiratory tract, the method comprising metering into the nose of a mammal in need thereof a therapeutically effective amount of budesonide that is less than about 320  $\mu\text{g}$  per day, delivered as 8 or more unit doses in a metered amount of about 32  $\mu\text{g}$  budesonide per unit dose, wherein each unit dose comprises finely divided budesonide particles suspended in an aqueous medium having a pH between 3.5 and 5.0.

67. (New) The therapeutic method of claim 66, wherein the pH of the aqueous medium is between 4.2 and 4.6.

68. (New) A therapeutic method according to claim 66, wherein the amount of budesonide is about 256  $\mu\text{g}$  per day.

69. (New) The therapeutic method of claim 66, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

70. (New) A unit dose of a therapeutic composition consisting of (a) about 32  $\mu\text{g}$  budesonide; and (b) other ingredients comprising

a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;

disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and

potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,

wherein the budesonide is in the form of finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

71. (New) The unit dose of claim 70, wherein the pH of the aqueous medium is between 4.2 and 4.6.

72. (New) A therapeutic method of treating conditions of the upper respiratory tract, the method comprising metering into the nose of a mammal a therapeutically effective amount of budesonide that is less than about 320 µg per day, delivered as 8 or more unit doses, wherein each unit dose consists of about 32 µg budesonide and other ingredients, the other ingredients comprising

a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;

dextrose;

Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;

disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and

potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,

wherein the budesonide is in the form of finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0.



73. (New) The therapeutic method of claim 72, wherein the pH of the aqueous medium is between 4.2 and 4.6.

74. (New) The therapeutic method of claim 72, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

75. (New) A unit dose of a therapeutic composition, the active ingredient of which consists of about 32 µg budesonide formulated as finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0, said composition being suitable for administration to a mammal in a single dose.

76. (New) The unit dose of claim 75, wherein the pH of the aqueous medium is between 4.2 and 4.6.

77. (New) The unit dose of claim 75, wherein the composition contains about 0.6 to 0.7 mg/ml budesonide.

78. (New) A therapeutic method of treating or preventing conditions of the upper respiratory tract, the method comprising administering into a nostril of a mammal a metered unit dose, the active ingredient of which consists of about 32 µg of budesonide formulated as finely divided particles suspended in an aqueous medium, having a pH between 3.5 and 5.0.

79. (New) The therapeutic method of claim 78, wherein the pH of the aqueous medium is between 4.2 and 4.6.

80. (New) The therapeutic method of claim 78, wherein the unit dose contains about 0.6 to 0.7 mg/ml budesonide.

81. (New) A therapeutic method of treating conditions of the upper respiratory tract, the method comprising metering into the nose of a mammal a therapeutically effective amount of budesonide that is less than about 320 µg per day, delivered as 8 or more unit doses, the active ingredient of each unit dose consisting of about 32 µg budesonide formulated as finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0.

82. (New) The therapeutic method of claim 81, wherein the pH of the aqueous medium is between 4.2 and 4.6.

83. (New) The therapeutic method of claim 81, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

84. (New) A unit dose of a therapeutic composition, the active ingredient of which consists of about 32 µg budesonide, wherein the therapeutic composition additionally comprises a mixture consisting of microcrystalline cellulose and sodium carboxymethyl cellulose, the mixture at about 0.5 to 2.5% by weight of the therapeutic composition;  
dextrose;  
Polysorbate 80 at about 0.005 to 0.5% by weight of the therapeutic composition;  
disodium edetate at about 0.005 to 0.1% by weight of the therapeutic composition; and  
potassium sorbate at about 0.05 to 0.2% by weight of the therapeutic composition,  
wherein the budesonide is in the form of finely divided particles suspended in an aqueous medium having a pH between 3.5 and 5.0, said therapeutic composition being suitable for nasal administration to a mammal in a single dose.

85. (New) The unit dose of claim 84, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 10 µm.

86. (New) The unit dose of claim 84, wherein at least 80% of the particles have a mass equivalent sphere diameter of less than 7  $\mu\text{m}$ .

87. (New) The unit dose of claim 84, wherein each unit dose contains about 0.6 to 0.7 mg/ml budesonide.

88. (New) A container containing budesonide and adapted to deliver the unit dose of claim 33.

89. (New) A container containing budesonide and adapted to deliver the unit dose of claim 34.

90. (New) A container containing budesonide and adapted to deliver the unit dose of claim 35.

91. (New) A container containing budesonide and adapted to deliver the unit dose of claim 52.

92. (New) A container containing budesonide and adapted to deliver the unit dose of claim 53.

93. (New) A container containing budesonide and adapted to deliver the unit dose of claim 70.

94. (New) A container containing budesonide and adapted to deliver the unit dose of claim 71.